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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,170	12/14/2001	Li Pan	(DI-5762) 112713-144	6401

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BAXTER HEALTHCARE CORPORATION
RENAL DIVISION
1 BAXTER PARKWAY
DF3-3E
DEERFIELD, IL 60015

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,170

Applicant(s)

PAN ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 and 31-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 28-30, drawn to a sensor for sensing ammonia in a fluid, classified in class 422, subclass 46.
 - II. Claims 10-27, drawn to a sensor for dialysis system, classified in class 422, subclass 24.
 - III. Claims 31-38 and 49-53, drawn to a method of sensing ammonia in a dialysis system, classified in class 436, subclass 26.
 - IV. Claims 39-48, drawn to a method for performing dialysis, classified in class 600, subclass 36.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The invention of Group I comprises a fluid path and thus measures ammonia in a fluid flow, while the invention of Group II comprises a fluid container and thus measures optical property of a dialysate (or any other fluid) in a restricted volume.

Inventions III, IV and I, II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of Group I can be used for measuring ammonia in any liquid, rather than just dialysate, and the method of Group III can be performed with any ammonia sensitive device, which does not comprise membrane. The invention of Group IV can be performed with any membrane sensor, which does not change its optical property, but rather changes its weight, etc.

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Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions have different operation, different functions and different effects: while the invention of Group III measures the presence of a particular analyte, ammonia, the invention of Group III concerns measuring a change in pH of dialysate, without measuring any analyte.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Joseph P. Reagen on 11/19/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 28-30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-27 and 31-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not being written "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the invention in its best mode.

The specification discloses a numerous possible variations of sensors for dialysis system, which do not comprise clear and unambiguous embodiments due to too many possibilities for

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different arrangements of the sensors and potential analytes. It is difficult to understand what exactly the embodiments disclose, except for the ammonia sensor depicted on Figures 1-8.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-7, 9 and 28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash (US 4,661,246, IDS) in view of Khalil et al. (WO 01/35057 A2, IDS).

Ash discloses an ammonia sensor in dialysis system, comprising a fluid flow path, which is a portion of a dialysis system flow path, with an optical window 80, an ammonia test strip 78 comprising pH reagent and changing color when interacting with ammonia, and an optical reader

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77 outside the flow path, which identifies the change of the strip, and a processor 66. The strip is illuminated by a red-wavelength LED 76.

Ash does not specifically disclose pH sensitive hydrophobic membrane, a fluid pH conditioner or three color emitters connected to the processor.

Khali discloses "ammonia detection and measurement device", comprising Teflon (PTFE) hydrophobic membrane with pH sensitive reagent, which changes color upon reaction with ammonia. Khali emphasizes the preferences of such membrane since "the hydrophobicity of the PTFE provides a strong non-covalent bond to bond the dyes" (page 4, lines 19-23). Upon testing the prototype sensor "a buffered solution of ammonium chloride is made up at a known pH. From the known pKa and concentration of a NH_4Cl solution, one can predict the ammonia concentration in equilibrium with the solution" (page 6, lines 1-5). Khali further discloses different dye compositions for the membrane sensor, which may give absorbance in different spectral range.

It would have been obvious for anyone of ordinary skill in the art to substitute the paper pH indicator employed in Ash's sensor with Khali's hydrophobicity membrane exactly for the reasons indicated by Khali, i.e. because such membrane is much more stable and durable indicator than the paper strip. It would have been obvious to use the fluid pH conditioner to avoid changing pH of the fluid which is not caused by the presence of ammonia, as taught by Khali.

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash in view of Khalil, as applied to claims 1-7, 9 and 28-30 above, and further in view of Robinson et al. (US 4,350,660).

Although Ash in view of Khalil do not specifically disclose two color emitters connected to the processor, Khalil teaches various compositions for ammonia membrane sensor, which absorb in different visible ranges upon contacting ammonia. It would have been obvious for anyone of ordinary skill in the art to use two different color emitters in order to cover possible absorbance ranges for sensor membranes with various dye compositions.

Ash in view of Khalil do not specifically disclose an infrared emitter connected to the processor.

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Robinson discloses infra-red emitter for calibrating ammonia gas background (col. 2, lines 5-10).

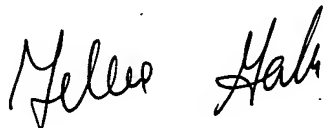
It would have been obvious for anyone of ordinary skill in the art to use IR emitter in Ash-Khali's method for the same reason Robinson used it in his ammonia sensor – to pre-calibrate the readings of the ammonia sensor by taking into account the absorbing background of the fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh
12/1/03

A handwritten signature in cursive script, appearing to read 'Yelena Gakh', written in dark ink.